

# PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number 033339/313045

(filed with the Notice of Appeal)

Application Number 10/596,789

Filed June 23, 2006

Confirmation No. 1481

First Named Inventor: Philippe Teissier

Art Unit 1794

Examiner: Hamid R. Badr

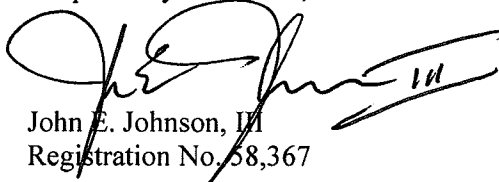
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

Respectfully submitted,



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Date October 25, 2011

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## REMARKS

Applicants submit that the final Office Action dated April 25, 2011, fails to establish a *prima facie* case of obviousness. In particular, Applicants submit that the currently pending claims are patentable over any combination of Santus (US 5,952,021 - R1) and Rutherford et al. (US 5,292,657 - R2).

### ***I. Rejections under 35 U.S.C. § 112***

Claim 11 has been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite because the term “before granulation” in Claim 1 allegedly does not have sufficient antecedent basis. Claim 11 was amended to recite that the particles of dehydrated bacteria have an average size of between 80 and 150  $\mu\text{m}$  prior to granulation.

The basis for the amendment of claim 11 can be found in the specification of the present application, see in particular paragraph [0029] of the US 2007/098847 application as published:

[0029] The average size of the particles of dehydrated bacteria (before their granulation) is preferably approximately between 80 and 150  $\mu\text{m}$ . In this regard, the size of the particles of dehydrated bacteria can optionally be adjusted, for example, by milling according to the conventional techniques well known to those skilled in the art.

### ***II. Rejections under 35 USC § 103(a)***

Claims 1, 3-5, 7-12, 16-19, and 21-22 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Santus (US 5,952,021 R1) in view of previously cited Rutherford et al. (US 5,292,657 R2). The Examiner argues that it would have been obvious to one skilled in the art to simply replace the CAP- or HPMCP-based enteric coating of R1 with the materials of R2, namely a fatty acid. See page 6 of the final Office Action.

Applicants submit that R1, R2, or any combination thereof fails to teach or suggest all aspects of the currently claimed invention. Additionally, Applicants submit that the proposed combination/modification of R1 with R2 is improper in view of at least R2's express teaching away from such a combination.

R1 is directed to a method to protect bioactive compounds and microorganisms from inactivation in the gastric tract. In particular, R1 describes the preparation of granules of microorganisms coated with a polymeric enteric coating; said coated granules having sizes ranging from 50 to 500  $\mu\text{m}$  and may be suspended in a liquid or semi-liquid food. Accordingly, R1 is directed to the encapsulation of microgranules of a bioactive material.

Applicants note that none of the coating material used in R1 is chosen amongst fat, food waxes, fatty acids and oils.

R2 describes the preparation of freeze-dried microorganisms entrapped in a fatty acid matrix capable of maintaining bacterial activity in acidic environment. R2 uses a specific process (different from the method used for preparing granules according to the currently claimed invention and that of R1) leading to the granules in which microorganisms are mixed and entrapped into the fatty acid matrix. Contrary to the compositions of R2, the currently claimed invention (as well as those disclosed in R1) is directed to the individual coating of particles of microorganisms. For instance, the currently claimed invention is directed to particles of dehydrated lactic acid bacteria **individually coated** (e.g., a plurality of particles are not mixed within a matrix) with vegetable fat solid at ambient temperature.

More specifically with regard to the teachings of R2, Applicants note that R2 only teaches a **dry food product** (i.e., not liquid food products as currently claimed) in which a microorganisms are incorporated. For instance, R2 states the following:

“It is important to note for purposes of this invention that **the free fatty acid does not individually encapsulate and form microcapsules of microorganisms. Instead, the product of the process of the present invention forms microspheres. A microsphere refers to a fatty acid matrix in which a plurality of microorganisms are incorporated. It is different from a microcapsule in which individual organisms are encapsulated. In a microsphere the fatty acid matrix functions for the composite similar to the relationship between a cookie dough matrix and chocolate chip cookies, with the chips representing a group of microorganisms, such as bacteria or yeast. Microcapsules will not work in the process of this invention, whereas microspheres do.**”

See column 1, lines 54-67 of R2 (emphasis added). That is, R2 explicitly (1) teaches that the compositions thereof are characterized as microspheres in which a plurality of microorganisms are mixed and held within a matrix; (2) that the microspheres are not the same or even equivalent to the individual encapsulation (i.e., microcapsules) of microorganism particles (as is the case in the currently claimed invention); and (3) that microcapsules (e.g., individually coated or encapsulated particles), such as the currently claimed invention, do not work. In this regard, Applicants note that R2 teaches away (discredits) the encapsulation of microorganisms with fatty acids as recited by the currently claimed invention.

***A. The combination of R1 and R2 fails to teach or suggest all aspects of the currently claimed invention***

Accordingly, Applicants note that the proposed combination of R1 and R2 does not disclose or suggest the currently claimed invention. More specifically, even if one tries to combine the liquid food product

described in R1 with the microsphere teachings of R2, the resulting food product (i) is not an aqueous beverage with a stable dispersion of granules; (ii) does not contain granules of encapsulated microorganisms having an average size of less than 200  $\mu\text{m}$  and (ii) does not contain granules with a core composed of dehydrated lactic acid bacteria and a coating layer of vegetable fat. Thus, even by combining the knowledge of R1 and R2, a person skilled in the art would not have prepared a liquid food product containing granules of probiotic microorganisms that are not perceptible in the mouth. Applicants submit, therefore, that the combination of R1 and R2 fails to disclose or suggest all aspects of the currently claimed invention. For at least this reason, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness.

***B. The proposed combination of R1 and R2 fails to establish a prima facie case of obviousness.***

In addition to not teaching or suggesting all aspects of the present invention, Applicants submit that the Examiner's proposed combination/modification of R1 in view of R2 is improper and fails to establish a *prima facie* case of obviousness.

In view of R2's express teaching highlighted above (i.e., column 1, lines 54-67), Applicants submit that the combination/modification proposed by the Examiner is improper for at least the following reasons in view of at least MPEP 2145:

(1) The cited art must be considered in its entirety including disclosures that teach away from the claimed invention, such as in the present case in which R2 teaches away from the claimed invention (i.e., granules of lactic acid bacteria encapsulated with at least one vegetable fat);

(2) It is improper to combine references where the references teach away from their combination, such as in the present case in which R2 teaches away from using fatty acids to encapsulate microorganisms as proposed by the Examiner; and

(3) Proceeding contrary to accepted wisdom is evidence of non-obviousness, such as in the present case in which the currently claimed invention proceeds contrary to accepted wisdom (as evident by R2) by encapsulating granules of lactic acid bacteria with a vegetable fat (which could be the very reason why R1 did not include fatty acids as a possible coating agent).

As previously noted, R2 clearly distinguishes microcapsules (individually encapsulated granules) from microspheres (plurality of particles mixed and contained within a matrix material). R2 also explicitly teaches that microcapsules (individually encapsulated granules) do not work and are, therefore, inferior to the use of microspheres (plurality of particles mixed and contained within a matrix material). Applicants note that the currently claimed invention recites individual particles of dehydrated bacteria coated with vegetable fat. As such, the currently claimed invention corresponds to microcapsules as defined and discredited by R2.

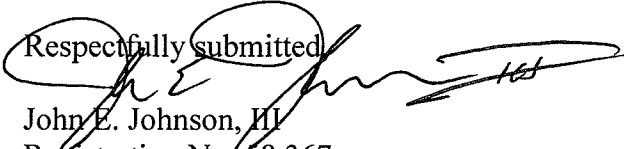
Applicants, therefore, submit that the cited art, when considered in its entirety including R2's explicit disclosure that teaches away from the currently claimed invention (i.e., individual granules of lactic acid bacteria encapsulated with at least one vegetable fat), cannot be construed/combined/modified in any manner that is in complete contradiction to the express teachings of R2 (e.g., microcapsules of fatty acids do not work).

In the same vein, Applicants submit that R2's express teaching away from the encapsulation of microorganisms with fatty acids renders the Examiner's proposed combination/modification of R1 with R2 improper. That is, R2 expressly teaches that the encapsulation of microorganisms does not work and is, therefore, inferior to the microsphere-based compositions. In this regard, the purported combination of references is not predictable in the fashion put forth by the Examiner and as required by KSR. In particular, it would not be predictable to substitute the fatty acid matrix material of R2 to the encapsulated particles of R1 as a coating agent for individual particles since R2 teaches away from such a combination. Indeed, in KSR in the context of the importance of predictability with respect to propriety of a combination of references, the Supreme Court extensively discusses U.S. v. Adams, 383 U.S. 39 (1966). In U.S. v. Adams, the Supreme Court found the claims not to be obvious even though the claims were drawn to a structure already known in the art that was altered by the substitution of one known element with another with predictable results since the prior art taught away from combining certain ones of the known elements. *Id.* at 50-52. Moreover, as a matter of practice, MPEP § 2143 describes a number of different rationales for obviousness and requires an Examiner to articulate a number of findings to support an obviousness rejection including, in most instances, a finding that the proposed modification or combination would have been predictable to one of ordinary skill in the art. Consistent with the guidance provided by KSR, MPEP § 2143 also repeatedly notes that obviousness cannot be established under a respective rationale in instances in which an Examiner fails to properly establish any one of the requisite findings, such as in the present application in which the combination of R1 and R2 does not provide predictable results in light of R2's express teaching away. Any such combination of R1 and R2 lacks a rational basis or expectation of success in light of R2's express teachings.

### ***III. Conclusion***

Applicants submit that the cited art does not render obvious any of the currently pending claims. Accordingly, the obviousness rejections as well as the rejection under 35 U.S.C. § 112 should be withdrawn.

Respectfully submitted,

  
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Date October 25, 2011